

## **REMARKS**

The present application is directed to a method of producing a protective immune response in a mammal by administering to the lung of the mammal an aerosol containing biodegradable microspheres that include a non-living reagent that produces a protective immune response in a mammal to which it is administered.

Upon entry of the foregoing amendment, Claims 17-27 will be pending. Claims 1-16 have been canceled without prejudice. New Claims 18-27 have been added. No new matter is added.

### **Specification**

Applicants have amended the specification to correct typographical and spelling errors including those requested by the Examiner. Applicants respectfully submit that upon entry of the amendments, the informalities in the specification objected to by the Examiner will have been rectified.

### **Drawings**

Replacement Sheet 2/3 is submitted herein pursuant to 37 CFR 1.21(d) to replace Figures 2 and 3. In Figure 2, the spelling of "TITER" is corrected as directed by the Examiner, and in Figure 3, the spelling of "IMMUNIZED" is corrected as directed by the Examiner.

### **Claim Objections**

Claims 2 and 10 have been canceled, thereby rendering the objections to these claims moot.

### **Rejection under 35 USC §112, second paragraph**

Claim 13 has been canceled, thereby rendering the rejection of this claim moot.

## Rejections under 35 USC §102(b)

Claims 1-14 and 17 were rejected under 35 U.S.C. §102(b) as anticipated by Eyles *et al.* (*Vaccine* 19:4732-4742, 2001). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 1-14 have been canceled, and Claim 17 has been amended to clarify that the method of producing a protective immune response in a mammal involves **administering to a lung** of the mammal a protective amount of an **aerosol** containing biodegradable microspheres of an average diameter of from 0.5 to 5  $\mu\text{m}$  comprising a non-living reagent that produces a protective immune response in a mammal to whom it is administered.

Eyles *et al.* is a scientific paper researching the translocation of microspheres following **intranasal** delivery of a vaccine to mice. Applicants respectfully submit that intranasal administration is different from pulmonary delivery by **aerosol administration to the lung**, as claimed in amended Claim 17. Eyles *et al.* teach that the type of tissue to which the microspheres are administered is important in determining the nature of the immune response generated, and an important tissue type investigated is nasal associated lymphoid tissues (NALT). Therefore, it would not be anticipated nor obvious from the teachings of Eyles *et al.* to change administration from nasal administration to pulmonary administration to the lung. This is made clear by statements made on page 4740, column 2, line 49, to page 4740, column 1, line 11 of Eyles *et al.*, which explicitly report that the implications of their research findings for the design of mucosal immunization strategies, “particularly where vaccines are delivered to the lungs by aerosolisation, using clinically relevant delivery systems and antigens,” remain **unclear**.

In addition, the term “aerosol” is defined on page 2, lines 10-11, of the present application as a formulation that is deliverable in the form of a dispersion of a solid and/or liquid **in a gas**. In contrast, Eyles *et al.* teach nasal administration to anaesthetized mice of microspheres in phosphate buffered saline (PBS), which is a **liquid** solution. It is not delivered in the form of an **aerosol** as claimed in amended Claim 17.

For at least the foregoing, applicants respectfully submit that Eyles *et al.* fail to teach the method of amended Claim 17 and request withdrawal of the rejection under 35 U.S.C. §102(b).

**Rejections under 35 USC §103(a)**

Claim 15 was rejected under 35 U.S.C. §103(a) as obvious over Eyles *et al.* in view of U.S. Patent No. 6,098,619 to Britto *et al.*

Claim 15 has been canceled, thereby rendering the rejection moot.

For at least the foregoing, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

## **CONCLUSION**

The foregoing is submitted as a full and complete response to the Office Action mailed April 2, 2007.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 745-2473 is respectfully solicited.

No additional fees are believed due; however the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account number 11-0855.

Respectfully submitted,

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